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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,203	09/22/2006	Yoshinobu Yamazaki	Q96974	5777

23373 7590 07/28/2010

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EXAMINER	
PAGONAKIS, ANNA	

ART UNIT	PAPER NUMBER
1628	

NOTIFICATION DATE	DELIVERY MODE
07/28/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/599,203	YAMAZAKI ET AL.	
	Examiner	Art Unit	
	ANNA PAGONAKIS	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *1-10,15,16 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-14, 17 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's payment and submission filed 4/5/2010, has been received and entered into the present application. Accordingly, prosecution has been reopened.

Applicant's arguments filed 4/5/2010 have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Status of Claims

Claims 1-19 are currently pending.

Claims 1-10, 15-16 and 18 remain withdrawn from consideration.

Claims 11-14, 17 and 19 are currently under examination and the subject matter of the current Office Action.

Necessitated by amendment:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-14, 17 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in

the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, has possession of the claimed invention.

Present claim 11 is directed to a method for the treatment of urinary frequency or incontinence, comprising administering to a subject *not having benign prostatic hyperplasia or symptomatic prostatism* a phenoxyacetic acid derivative represented by formula (I) in combination with an alpha1-adrenoreceptor blocker (emphasis added).

In particular, the specification and claims as originally fail to provide adequate written description for the newly added claim 11. Applicant has guided the Examiner to paragraph [0023] for support of the amendment "not having benign prostatic hyperplasia or symptomatic prostatism." Paragraph [0023] teaches:

> [0023]
>
> The combined use of the phenoxyacetic acid derivative and the α1-AR blocker remarkably decreases the intra-bladder pressure or remarkably prolongs the micturition interval, and therefore, exerts extremely high efficacy for the prevention or treatment of bladder neurosis, nocturia, pollakiuria accompanied with prostatic hypertrophy or the like, or incontinence accompanied with the same; idiopathic pollakiuria or incontinence accompanied with the same; or urinary frequency or incontinence accompanied with neurogenic bladder dysfunction, unstable bladder, bladder spasm, chronic or acute cystitis, chronic or acute prostatitis or the like. Thus, it is expected to be an effective therapeutic agent for a patient who can not obtain a sufficient efficacy by using a single drug, a patient who desires dose reduction of a drug used for the disease and the like.

The above cited passage does not seem to teach a positive or negative recitation of the amended claim limitation. A review of the disclosure does not teach the treatment of "symptomatic prostatism." While it is recognized that adequate written description of a limitation is not required to be stated *in haec verba* in

the specification or claims as originally filed, adequate written support for all claim limitations must arise from either an explicit or an implicit suggestion by the disclosure to show that such a concept as now claimed was actually in possession of the Applicant at the time of the invention.

MPEP §2163 states, "The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test of sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983))...Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991)."

Accordingly, the claims are considered to lack sufficient written description and are properly rejected under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 103

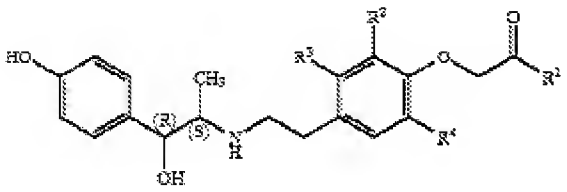
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11-14, 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al (WO 00/02846, cited as a functional language equivalent is U.S. 6,538,152) in view of Garvey et al. (U.S. 2002/0143007) as evidenced by Mesh Supplementary Data (2009; of record) and Guittard et al. (U.S. 6,262,115).

Tanaka et al teach the administration of the compound:



where R2 and R3 are ach lower alkyl groups and pharmaceutically acceptable salts thereof, for the treatment of urinary incontinence (abstract).

Garvey et al. teaches a method for the treatment of an overactive bladder with the administration of an alpha-adrenergic receptor antagonist such as KMD-3213 (claims 36 and 38). The usual doses of alpha-adrenergic receptor antagonists are about 1 mg to about 100 mg per day, preferably about 0.5 mg to about 10 mg per day (paragraph [0256]).

Mesh Supplementary data teaches that KMD-3213 is an alternative name for silodosin.

Guittard et al. teaches that involuntary urinary incontinence is also known as urge incontinence and overactive bladder (column 1, lines 55-56).

Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the references so as to administer silodosin (alpha-adrenoreceptor antagonist) in combination with ethyl(-)-2-[4-[2-[[(1S,2R)-2-hydroxy-2-(4-hydroxyphenyl)-1-ethylethyl]amino]ethyl]-2,5-dimethylphenoxy]acetate in view of teachings of Tanaka et al and Garvey et al. One would have been motivated to do so because each of the therapeutics have been taught in the prior art to be useful for the treatment of urinary incontinence. Further, Guittard et al. teaches that urinary incontinence is alternatively known as an overactive bladder. Therefore, the idea of combining administration of the two agents flows logically from their having been taught in the prior art. Applying the same logic to the instant claims, one of ordinary skill in the art would have been imbued with a reasonable expectation of success that administration of both agents would be useful for the treatment of urinary incontinence.

With respect to claim 17, the determination of a dosage having the optimum therapeutic index while minimizing adverse and/or unwanted side effects is well within the level of the skilled artisan. The dosage is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would have been obvious for a person of ordinary skill to determine the optimal dosage needed to achieve the desired results. Thus, absent some

demonstration of unexpected results from the claimed parameters, the optimization of dosages would have been obvious at the time of Applicant's invention.

Applicant's Remarks

It should be noted that arguments previously presented by Applicant will not be addressed herein as not to burden the record.

Applicant alleges that no report shows that silodosin has an inhibitory activity against contraction of the bladder, whereas silodosin was known to suppress uretheral contraction and be useful as an agent for the treatment of dysuria. This is not found to be persuasive. Applicant is guided to the breadth of their own claim. The claim is not drawn to the inhibition of contraction of the bladder, rather the claim is drawn to the treatment of urinary frequency or incontinence. Further, Garvey et al. teaches the treatment of overactive bladder (i.e. urinary incontience, per Guittard et al.) with administration of silodosin, in contrast to Applicant's allegations.

Applicant alleges that the acetic acid-stimulated frequency model is a frequency model independent of the presence or absence of urinary obstruction. Applicant guides the examiner to the table on page 11 of the response in support that the change in micturition interval yields an unexpected and synergistic result. Firstly, it is noted that Applicant has not set forth that the acetic acid-stimulated frequency model is in fact a model that is predictive of urinary obstruction. Further, it should be noted that the table on page 11 is drawn to:

(i) the combination of compound 2 and silodosin;

(ii) a dosage of 0.03 mg/kg of silodison and 1 mg/kg of compound 2.

It should be noted that the above results are not commensurate in scope with present claim 11. The claim is drawn to the combination of a compound of formula (I) and an alpha-adrenoceptor blocker. Applicant has not set forth any explanation or reasoning as to how the above combination and the accompanying dosages are commensurate in scope with the combination of claim 11.

Conclusion

No claim is found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNA PAGONAKIS whose telephone number is (571)270-3505. The examiner can normally be reached on Monday thru Thursday, 9am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AP
/Brandon J Fetterolf/
Primary Examiner, Art Unit 1642